UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

ASTELLAS INSTITUTE FOR REGENERATIVE MEDICINE, and STEM CELL & REGENERATIVE MEDICINE INTERNATIONAL, INC.,

Plaintiffs,

v.

IMSTEM BIOTECHNOLOGY, INC., XIAOFANG WANG, and REN-HE XU,

Defendants.

C.A. No. 1:17-cv-12239

DEFENDANTS' REPLY TO ASTELLAS' OPPOSITION TO DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT

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Defendants Imstem Biotechnology, Inc. ("Imstem"), Xiaofang Wang ("Wang"), and Ren-He Xu ("Xu") (collectively, "Defendants") submit the following Reply to Plaintiffs' Opposition to Defendants' Motion for Partial Summary Judgment. (Dkt. 142).

I. PLAINTIFFS HAVE NOT SOLVED THEIR STATUTE-OF-LIMITATIONS PROBLEM

A. Tort Claims

The starting point for Plaintiffs' statute-of-limitations ("SOL") argument is that the earliest mere "hint" of Defendants' misdeeds was February 4, 2014. (Opp. 1 at 3).

Not true. For starters, Defendants had "anticipated litigation" against the Defendants and engaged counsel on June 28, 2013, *i.e.* the very same day they learned that Wang and Xu had founded ImStem to develop hESC-derived MSCs. *See* Corr. SMF (Dkt. 137) ¶¶ 17-18

); Supp.

Shannon Decl.² Ex. 2 (excerpt of Plaintiffs' privilege log re: June – Sept. 2013 indicating retention of counsel).³ According to Plaintiffs' privilege log, there were eight communications in June 2013 and September 2013 – more than four years before the Complaint – among Dr. Kimbrel, Mr. Vincent, a lawyer, and an IP consultant concerning "legal advice" or "legal strategy" concerning "anticipated litigation." *Id.* The leaders of Astellas knew that Wang and Xu had formed ImStem.⁴ They knew that ImStem was operating in "their" field. They believed

¹ Pls' Mem. in Oppn. to Defs' Motion for Partial Summary Judgment (Dkt. 142).

² Supp. Decl. of Timothy R. Shannon in Supt. of Defs' Mot. for Summary Judgment.

³ Defendants identified these privilege log items by email to Plaintiffs on December 23, 2019, indicating they planned to use them in the event Plaintiffs denied having earlier knowledge of their claims against Defendants and invited Plaintiffs to address them in the Opposition. Suppl. Shannon Decl. Ex. 3 (email from Shannon to Sharkey dated Dec. 23, 2019 re: "Additional evidence"). *Cf.* Corr. Br. (Dkt. 135) at 4, 13; Corr. SMF ¶ 22; Corrected Declaration of Timothy R. Shannon in Support of Defendants' Motion for Summary Judgment ("Corr. Shannon. Decl.") Ex. 25 (previously filed excerpt of Plaintiffs' privilege log re: Feb. 2014).

⁴ The corporate distinctions between ACT, then Ocata Therapeutics, Inc., then Astellas Institute for Regenerative Medicine ("Astellas") are immaterial to the summary judgment papers.

that Drs. Wang and Xu had no experience making MSCs, nor testing them for therapeutic effect, nor experience treating multiple sclerosis before learning of Dr. Kimbrel's protocol (according to Astellas years later). Astellas' SMF ¶ 38⁵; Opening Expert Report of Lisa Fortier, DVM, Ph.D (October 4, 2019) at 53. Yet they now knew that Wang and Xu were starting a company in precisely the same space as the collaboration and pursuing patents. Plaintiffs knew they had potential non-inventorship claims against the Defendants, hence their retention of counsel for "anticipated litigation." Plaintiffs' privilege log precludes any other argument; it is a party admission of actual knowledge of the tort claims.⁶

Nor was the '551 PCT (published as WO2014/011407) merely "similar" to the '551 patent application that triggered the instant suit (Dkt. 1, ¶ 62) (contending that Plaintiffs "became aware of Defendants' intended wrongful use . . . around July 2015, when the patent application publication for Defendants' '551 patent . . . published") or the '551 Patent itself, which they now seek to commandeer. The '551 PCT that was discovered by Astellas in 2014 (Corr. SMF ¶ 21), the national-stage '551 non-provisional (*i.e.* the "'551 National Stage Application") discovered in 2015 (Dkt. 1, ¶ 62), and the resulting '551 Patent issued in 2017 (Corr. SMF ¶ 35) are identical in every material respect. Plaintiffs' downplay and label that identity as mere "similarity" but on closer inspection Plaintiffs never actually dispute the fact. *See* Pls' Resp. to Def.'s Corr. SMF ¶ 15 (failing to respond to Defendants' assertion of identity of disclosures), ¶

⁵ Astellas' Statement of Undisputed Material Facts in Supt. of Its Mot. for Partial Summary Judgment (Dkt. 130).

⁶ Plaintiffs have not disputed the binding effect of its own privilege log representations. In the Corr. SMF, Defendants pointed out a similar admission in connection with Astellas' internal discussions in February 2014. *See* Corr. SMF ¶ 22. Astellas' response never mentions the privilege log, nor disputes that it indicates exactly what it says: that Astellas was anticipating litigation. *Cf.* Pls' Resp. to Def.'s Corr. SMF (Dkt. 144) ¶ 22. *See also Siemens v. Seagate Tech.*, No. SACV 06-788JVS ANX, 2009 WL 8762978, at *9 (C.D. Cal. Apr. 27, 2009) (finding a privilege log admissible).

⁷ Opp. at 4 (the published PCT application . . . has a similar disclosure to Defendants' '551 patent'); First Amen. Compl. (Dkt. 114) ¶ 62 (similar).

22 (same).⁸ It should be deemed admitted.

The Court can confirm it with a simple comparison. The Abstract of the '551 PCT reads:

The present invention relates to methods of generating and expanding hitman [sic] embryonic stem eel! [sic] derived mesenchymal-iike [sic] stem/siromal cells. These hES-MSCs are characterized at least in part by the low level of expression of IL-6. These cells are useful for the prevention and treatment of T cell related autoimmune disease, especially multiple sclerosis . . .

'551 PCT (Corr. SMF ¶ 20; Corr. Shannon. Decl. Ex. 23) at Abstract. This was and is identical to the Abstract in the '551 National Stage Application, right down to the same typographical errors. *Compare* '551 PCT (Corr. SMF ¶ 20; Corr. Shannon Decl. Ex. 23) at Abstract, *with* '551 National Stage Application (Corr. SMF ¶ 21; Corr. Shannon Decl. Ex. 31) (identical, word for word). To call these "similar" is misleading at best; they're the same. The '551 PCT likewise disclosed exactly the same hESC-EB-HB-MSC four-step process that Plaintiffs' would claim as their own . . . three-and-a-half years later:

The present invention relates to a method of generating mesenchymal stem cells from human embryonic stem cells using a multi-step method of culturing embryonic stem cells . . . under conditions sufficient to produce embryoid bodies, culturing the embryoid bodies under conditions to expand hemangio-colony forming cells in the medium comprising the embryoid bodies, and culturing the hemangio-colony forming cells under conditions that induce differentiation into mesenchymal stem cells.

'551 PCT (Corr. SMF ¶ 20; Corr. Shannon Decl. Ex. 23) at Introduction. *Compare* '551 PCT at 16 − 21 (illustrating Defendants' description of their intended process for generating MSCs

⁸ See also Corr. SMF ¶15 n. 18 (citing Deposition Transcript of Bryan Daniel Zerhusen, Ph.D., J.D. at 101 − 04 (Nov. 22, 2019)) ("Q. Just so I understand what you said, both as a matter of comparing the documents and Patent Office procedure, the specification and figures in defendants' PCT application are identical to the specification and figures in their U.S. application; is that right? A. That's correct. It's the same specification."); Supp. Shannon Decl., Ex. 1 (Expert Report of Bryan Zerhusen (Nov. 1, 2019); id. ¶ 35 (opining that if Plaintiffs' confidential information was in the '551 patent, it was necessarily in the '551 PCT Application); id. ¶ 36 (same).

through a hemangioblast intermediary) with '551 National Stage Application (Corr. SMF ¶ 21; Corr. Shannon Decl. Ex. 31) ¶¶ 0092 – 105 (illustrating the same, with the exact same language.) 9

Put simply, the evidence establishes beyond refutation that Plaintiffs knew in February 2014 the basis of their tort claims. The '551 PCT that Mr. Vincent found alarming enough to alert counsel in February 2014 (Corr. SMF ¶ 22) *was* the corresponding national stage patent application for '551 Patent, which served as the basis for Plaintiffs' tort claims in their 2017 Complaint. The '551 PCT was not a "hint." It was a thunderclap. Astellas could see it had a claim that technology had been stolen. The claim accrued. ¹⁰

Put differently, if Astellas had a Rule 11 basis for filing suit in November 2017 for its tort claims, it had had that same basis since February 2014. Astellas could have filed suit in February 2014. It chose not to.¹¹

Astellas' go-to case, *Mass. Eye & Ear Infirmary v. QLT Phototherapeutics, Inc.*, 412 F.3d 215 (1st Cir. 2005) ("*MEEI*") is distinguishable for this reason, among others. In *MEEI*, the

Corr. SMF ¶ 24 (Email from Mike Vincent to Mike Heffernan (June 5, 2014 3:25 PM)) (emphasis added).

⁹ As indicated in Corr. Br. (Dkt. 135) 3-4, n. 6, the rules governing patent prosecution do not allow an applicant for patent to add new subject matter to a PCT, or national stage ("non-provisional") patent application after its filing date. Therefore, the '551 PCT and the '551 National Stage Application were legally required to be the same.

¹⁰ Indeed, according to the original Complaint, the accused taking-of-technology (however framed) took place the moment Xu and Wang filed and claimed as their own the provisional patent application, asserting ownership over Astellas' technology.

Astellas likewise leaves largely unaddressed the flurry of activity in June 2014, including

plaintiff asserted breach of contract, breach of implied contract, conversion, ¹² trade secret misappropriation arising out of the defendant's licensing their jointly-developed technology to a third-party without permission. *Id.* 412 F.3d at 225, 228 – 43. The First Circuit found that the statute of limitations should have been be tolled because (1) the defendant repeatedly assured plaintiff that it was not disclosing trade secrets while nonetheless disclosing them bit by bit over a matter of years; (2) plaintiff had no more than a mere suspicion that defendant was disclosing the trade secrets. These facts are simply not present in the instant case. Aside from the lack of repeated assurances (rather, stony silence in most emails), Astellas has admitted it had *actual knowledge* of facts sufficient to anticipate litigation long enough to be barred by the statute of limitations. *Cf. MEEI*, 412 F.3d at 239 ("The statute of limitations, however, is not tolled if the plaintiff has actual knowledge of the facts giving rise to his cause of action"). The formation of ImStem, the retention of counsel, the '551 PCT – none of this was mysterious, none of it a slow drip. Astellas knew. Astellas nonetheless waited.

Further, Astellas' repeated observation that litigation has revealed more details about the misappropriation of its protocol is unavailing. *See* Corr. Br. at 12 (citing cases); *see also Olsen v. Bell Tel. Labs., Inc.*, 388 Mass. 171, 175, 445 N.E.2d 609, 612 (1983) ("If knowledge of the extent of injury were to control the accrual of a cause of action, the fixed time period of statutes of limitations effectively would be destroyed.") Discovery always yields more details, "the full extent" of alleged misdeeds. *Cf.* Opp. 4. The formation of ImStem, predicated on Astellas' technology (as we assume for purposes of this portion of the Motion), ¹³ was actionable in June

¹² The Court held that Mass. EEI's conversion claim must fail, as QLT was owner the inventive aspects of the '349 patent, and therefore had a right to independently exploit the rights of the '349, and thus could not "wrongfully exercise acts of ownership" over the patent. *MEEI*, 412 F.3d at 230 (emphasis in original).

¹³ Astellas' characterization of ImStem as "founded" on Astellas' technology is overwrought, even by the standards of summary judgment. The only evidence to which Astellas has ever pointed is a March 2012 business plan that the lead investor testified he never read. Likewise, Astellas presents no evidence – other than Dr. Fortier's conclusory

2013 when Astellas knew that ImStem had formed a company for hESC-MSCs to treat multiple sclerosis, the subject of *inter alia* Astellas' '956 patent. The discovery of the '551 PCT removed any doubt. The details of Dr. Wang's investor presentations is irrelevant for SOL purposes.

Nor does Astellas' "fiduciary relationship" argument save its untimely claim. As a preliminary matter, the argument is simply a bootstrapped version of the contract claim. Opp. at 8 ("The parties entered into a valid contract . . . establishing a fiduciary duty"). It fails if and as the contract claim fails. Indeed, even the Court concludes that there was contract here (it should not), it would not give rise to the higher "fiduciary duty." *See, e.g., UBS Fin. Servs., Inc. v. Aliberti*, 483 Mass. 396, 409, 133 N.E.3d 277, 290 (2019). Dr. Wang's stony silence and Dr. Xu's glib one-liner ("I don't think . . .") hardly demonstrate a deep bond of trust. No reasonable jury could find that three terse, partly-answered, ambiguous email exchanges gave rise not just to a contract but a relationship of trust and confidence sufficient to impose a fiduciary duty. Quite the opposite. Plaintiffs were seeking reassurances and agreements (in vain) precisely because the parties did not have trust and confidence in each other.

B. 93A Claim

Astellas says little about the 93A claim in its Opposition, and nothing rebutting the Defendants' arguments concerning Plaintiffs' knowledge of their claim in mid-2013. Opp. at 12-13. To the extent Astellas has responded by reference, *see id.*, it bears repeating that Astellas'

assertions – that T-MSC technology has anything to do with MSC technology. The Court can indulge evidence a certain amount of favorable light, not unmoored statements.

¹⁴ We note that Astellas did not raise this argument during written discovery – a position that would presumably earn the Defendants a bold, italicized admonition in the brief if the tables were turned. Nonetheless, Defendants have no procedural objection. The argument is simply wrong on the merits.

¹⁵ See generally Rodi v. S. New England Sch. of Law, 532 F.3d 11, 15 (1st Cir. 2008) ("if no reasonable jury could find the party's reliance reasonable a court may grant summary judgment")

own privilege log belies its argument. The log not only shows activity in response to the June 27, 2013 discovery of ImStem's founding, it shows legal activity and the awareness of "anticipated litigation." Supp. Shannon Decl. Ex. 2 (excerpts of Astellas privilege log). This is enough. *Bowen v. Eli Lilly & Co.*, 408 Mass. 204, 207, 557 N.E.2d 739, 741 (1990) ("The important point is that the statute of limitations starts to run when an event or events have occurred that were reasonably likely to put the plaintiff on notice that someone may have caused her injury."). Actual knowledge forecloses any tolling argument. *MEEI*, 412 F.3d at 239.

C. Unjust Enrichment

Astellas' primary argument with respect to its unjust enrichment is that the claim survives because it sounds in contract. *See* Opp. at 11, an implicit admission that the tort claims are doomed. The argument fails. The unjust enrichment Count says nothing about breach of contract. *See* Amend. Compl. (Dkt. 113) ¶¶ 64-70. It refers only to the receipt of intellectual property, *id.* ¶ 65, and the only detailed allegation is of "unlawful[] use [of] Plaintiffs' property by asserting inventorship . . . and deriving an unjust benefit from exploiting Plaintiffs' inventions." *Id.* ¶ 68. For a claim allegedly grounded in "contract," the recitation of tort steps and the complete absence of the word, "contract," is rather striking. The Count sounds in tort. It is time-barred for the reasons set forth above.

II. SUMMARY JUDGMENT IS APPROPRIATE ON PLAINTIFFS' ELEVENTH-HOUR BREACH OF CONTRACT CLAIM

A. Defendants Properly Disclosed Their Defenses During Discovery

Plaintiffs reprise an argument, first made in their own motion for partial summary judgment (Dkt. 128), that Defendants "failed to disclose or provide *any* factual evidence to support its affirmative defense theories during discovery." (Opp. at 13) (emphasis in original). Defendants incorporate and refer the Court to the portion of their Opposition to that motion that

explains why Plaintiffs are wrong. ¹⁶ See Defendants' MSJ Opp. at 12-15. The thinness and incoherence of the underlying "contract" emails is itself evidence for the affirmative defenses.

A. The Contract Claim is Ripe for Judgment as a Matter of Law Because There Are No Genuine Issues of Material Fact

Buried among Astellas' pell-mell accusations of flouted orders and discovery disconnects is the striking admissions that (1) the "key" facts are not disputed, Opp. 14, and (2) the parties' disagreement is over the "interpretation" (*i.e.*, the legal effect) of those undisputed facts, Opp. 15. Because the existence of a contract is a matter of law, the Court can resolve this aspect of the dispute on summary judgment.

Plaintiffs allege – and Defendants agree – that the "contract" at issue consists of three email exchanges: March 2011, December 2011, and April 2012. *See* Opp. at 14-15 (stating that Plaintiffs' contract clams "arises out of" three "key" email exchanges); Astellas' SMF ¶¶ 83-90; Corr. Br. at 18-19; Corr. SMF ¶¶ 3-6). The parties therefore do not dispute the "evidentiary foundation" of the alleged contract. (Opp. at 14-15) (characterizing parties' disagreement as over their "view" of the "evidence" and their "interpretation" of "material facts")). Moreover, neither party claims that the alleged contract is ambiguous. (Opp. at 16-17) (arguing that the emails "address" the essential "terms" of the purported contract).

The Court can therefore review the three emails and determine, as a legal matter, whether

¹⁶ Plaintiffs' focus on Defendants' "affirmative defenses" obscures the fact that it is <u>Plaintiffs' burden</u> to prove the existence of a valid and binding contract. Thus, whether cast as affirmative defenses or simply an inability of Plaintiffs' to meet their burden, Defendants' arguments get to the same point – that Plaintiffs cannot, as a matter of law, carry their burden and summary judgement is therefore appropriate.

¹⁷ Nor can Plaintiffs argue that their disagreement with how to "interpret" the plain language of the emails makes the "contract" ambiguous. *See*, *e.g.*, *Boazova v. Safety Ins. Co.*, 462 Mass. 346, 351 (2012) (quoting *Citation Ins. Co. v. Gomez*, 426 Mass. 379, 381 (1998)) ("an ambiguity is not created simply because a controversy exists between the parties, each favoring an interpretation contrary to the other."); *see also FDIC v. Singh*, 977 F.2d 18, 22 (1st Cir. 1992) (finding that a contract is not ambiguous merely because a party to it, often with a rearward glance colored by self-interest, disputes an interpretation that is logically compelled); *Wyner v. N. Am. Specialty Ins. Co.*, 78 F.3d 752, 756 (1st Cir. 1996) ("[a]n ambiguity is not created merely because a controversy exists between parties, each favoring an interpretation contrary to the other.") (citation omitted).

they form a binding and enforceable contract. *See, e.g., TLT Const. Corp. v. RI, Inc.*, 484 F.3d 130, 135 (1st Cir. 2007) ("where the evidentiary foundation for determining the formation of the parties' contract is either undisputed or consists of writings, contract formation is instead a question of law for the court"); see also *Nadherny v. Roseland Prop. Co., Inc.*, 390 F.3d 44, 48 (1st Cir. 2004) (finding that, under Massachusetts law, contract interpretation is ordinarily a matter of law); *Moore v. La–Z–Boy, Inc.*, 639 F.Supp.2d 136, 140 (D. Mass. 2009) (holding that where material facts are not in dispute, it is for the court to determine whether a contract has been formed); *Cataldo Ambulance Serv., Inc. v. City of Chelsea*, 426 Mass. 383, 387 (1998) (whether a contact is formed can be a question of law). Whether the three emails constitute a contract (Opp. at 14-16) is, in reality, a legal – not a factual – question.

The cases that Plaintiffs cite in their brief underscore this point. *See Feldberg v. Coxall*, MICV201201649A, 2012 WL 3854947, at *5 (Mass. Super Ct. May 22, 2012) (whether emails constitute a contract and satisfy the Statute of Frauds is a "difficult legal question"); *Fecteau v. Benefits Grp., Inc. v. Knox*, 72 Mass. App. Ct. 204, 212 (2008) (appellate court conducted "de novo" review of trial court's determination whether email terms constitute a "sufficiently clear and complete agreement"); *see also Corp. Dev. Associates v. Staples*, No. MICV201100958F, 2013 WL 597488, at *5 (Mass. Super. Ct. Jan. 31, 2013) (granting summary judgment "as a matter of law" because court found that emails did not constitute a sufficiently definite legal agreement, there was no acceptance, and the Statute of Frauds was not satisfied).

The "factual disputes" that Plaintiffs identify are, in reality, legal questions. For example, Plaintiffs argue that the three emails contain "essential terms" of a contract, and suggest that Defendants' disagreement creates a factual dispute. (Opp. at 16-17). This is just another way of articulating the legal dispute over contract formation. Whether the terms of a

purported contract are sufficiently definite to be enforceable is a question of law for the Court. *See, e.g., Armstrong v. Rohm & Haas Co.*, 349 F.Supp.2d 71, 78 (D. Mass. 2004). Likewise, Plaintiffs argue that Dr. Xu and Wang's responses to different emails, at different times, and discussing different issues give rise to a genuine factual dispute. (Opp. at 17-19). If the Court concludes that the emails do not constitute a contract, the issue of "assent" is irrelevant. Further, there is no dispute of fact; both parties point to Dr. Xu's response in the December, 2011 email and Dr. Wang's response to the April, 2012 email. (Opp. at 18-19). Rather, the dispute is over the legal import of those undisputed facts.

Plaintiffs only decided to bring their breach of contract – nearly two years into the case – to avoid Defendants' SOL argument and somehow preserve a state law claim. Plaintiffs have admitted as much. (Dkt. No. 97 at 8) ("Only after Defendants' [sic] raised their statute of limitations defense did Plaintiffs diligently reanalyze the evidence"); (Dkt. No. 1, ¶¶ 37, 42); (Dkt. No. 109 at 8-9). Now, faced with a question of law, Plaintiffs have resorted to recasting legal disputes as factual ones. It is time for this to end; none of the material facts are disputed and the Court should rule that Plaintiffs' contract claim fails as a matter of law.

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¹⁸ Plaintiffs suggest that the Statute of Frauds might not apply because the joint collaboration "could have been" completed in one year. (Opp. at 19). The application of the Statute of Frauds is a legal question. *See* Defendants' Corr. Br. at 20-21. There is nothing in the emails that suggests a timeframe for the expiration of any confidentiality requirement. At least one court (applying New York's Statute of Frauds, which is nearly identical to Massachusetts') held that an oral confidentiality agreement of an undefined duration violates the Statute of Frauds. *See Robins v. Zwirner*, 713 F. Supp. 2d 367 (S.D. N.Y. 2010). Confidentiality agreements of unlimited duration should not be exempt from the Statute of Frauds simply because the world could end within a year. Moreover, it is undisputed that the "joint collaboration" actually ran from June, 2010 and lasted until July, 2014. Ps' Resp. Corr. SMF at ¶ 1 (disputing scope of collaboration, not date), ¶ 30 (fact not disputed).

At various places on their brief, Plaintiffs point to extrinsic and parole evidence to support their position on the terms of the purported contract and any purported "assent." (Opp. 15, 17) (discussing snippet of Dr. Xu's deposition testimony). Similarly, Plaintiffs grasp at straws to argue that the meaning of Mr. Vincent's "opinion" creates a dispute as to a material fact. (Opp. at 19-20). Yet, despite the spin Plaintiffs put on it, the language of Mr. Vincent's email is plain, and it is an admission. With respect to Plaintiffs' identification of all of this extrinsic evidence, as discussed above, since – as the briefing turned out – neither party is arguing the purported contract is ambiguous, Dr. Wang's, Dr. Xu's and Mr. Vincent's *subjective* understanding of any purported agreement is immaterial for purposes of the Court's legal determination as to contract formation.

Dated: January 17, 2020 Respectfully submitted,

IMSTEM BIOTECHNOLOGY, INC.; DR. XIAOFANG WANG; and DR. REN-HE XU

By their attorneys,

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CERTIFICATE OF SERVICE

I hereby certify that on January 17, 2020, I caused a true copy of the <u>sealed</u> version foregoing document to be served upon all counsel of record via electronic mail, and will file a redacted version of the foregoing document in accordance with the Court's requirements.

/s/ *Timothy R. Shannon* Timothy R. Shannon